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10/522,197	02/17/2006	Toru Shinzato	NPR-163	1495
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KUBOVCIK & KUBOVCIK SUITE 1105 1215 SOUTH CLARK STREET ARLINGTON, VA 22202			CRONIN, ASHLEY L	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/522,197	<b>Applicant(s)</b> SHINZATO ET AL.
	<b>Examiner</b> ASHLEY CRONIN	<b>Art Unit</b> 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 1/24/2005.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-17 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 24 January 2005 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1668)  
Paper No(s)/Mail Date 3/7/2006; 4/13/2009

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "supporting means" and "the pin" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

2. The disclosure is objected to because of the following informalities: page 19 – is element 'B' supposed to be a pin or jig (line 4 or line 6); page 21, line 16 – "wind" should be "wing". Appropriate correction is required.
3. A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter. Specification appears to be a direct translation – missing essential words such as "the".

***Claim Objections***

4. Claim 1 is objected to because of the following informalities: line 9 - examiner suggests that "form an hole" should be changed to "form a hole". Appropriate correction is required.
5. Claim 9 is objected to because of the following informalities: line 5 – examiner suggests that "inserting indwelling" should be changed to "inserting an indwelling"; lines 8-9 – examiner suggests that "holding a indwelling needle" should be changed to "holding an indwelling needle". Appropriate correction is required.
6. Claim 11 is objected to because of the following informalities: line 7 – examiner suggests that "two spring parts" should be changed to "the two spring parts". Appropriate correction is required.
7. Claim 12 is objected to because of the following informalities: lines 3-4 - examiner suggests that "with driving means" should be changed to "with a driving means". Appropriate correction is required.

8. Claim 14 is objected to because of the following informalities: line 5 – “the tubular main body” – this is the first time that the main body is claimed as being tubular - examiner suggests that all claims containing main body use this language of “tubular” or the main body be properly recited as being tubular; line 10 – “with inclined plane facing a forwardly” is incomplete and indefinite. Appropriate correction is required.

9. Claim 16 is objected to because of the following informalities: line 3 – examiner suggests that “comprising wing holding means” should be changed to “comprising a wing holding means”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 9 recites the limitation “the supporting means” in line 4. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is indefinite whether applicant is trying to positively claim the pin for forming a hole for inserting an indwelling needle, since this element is only introduced within the preamble. However, the pin is referred to as part of the invention in claims 15-16, however, it is unclear whether the pin has any patentable weight since it is only introduced in the preamble of claim 9.

13. Claim 11 recites the limitation “the two spring parts” in line 5. There is insufficient antecedent basis for this limitation in the claim.

14. Claim 14 recites the limitation "the finger stop part" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.
15. Claim 14 recites the limitation "the spring" in line 4. There is insufficient antecedent basis for this limitation in the claim.
16. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether applicant is introducing a new element when claiming "the finger hook part" in line 13, or whether this is the same as "the finger stop part". For the purpose of examination, examiner will assume that the finger hook part and stop part are the same element.
17. Claim 16 recites the limitation "the wings" in line 4. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

19. **Claims 1, 3-7, and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Sasso (US Pat. No. 6,500,155 B2).**

20. Regarding claim 1, Sasso discloses a hole-forming pin 20 (Fig. 1) for inserting an indwelling needle comprising: a column-shaped insertion part 22 (Fig. 1) having a curved surface 22E (Fig. 1) at the distal end thereof, an insertion stop part 26 (Fig. 1) provided at the proximal end of the insertion part 22, and wings 28, 30 (Fig. 1) connected to the insertion stop part 26 (Fig. 1), the insertion stop part 26 and the wings 28, 30 are connected through elastic joint parts 32 (Fig. 1), said pin 20 can form a hole for inserting an indwelling needle for holding an indwelling needle from a skin surface to a blood vessel.

21. Regarding claims 3-7, Sasso further discloses wherein elastic deformation at the elastic joint parts 32 (Fig. 2) is such that the entire wings 28, 30 can be moved in the direction of right angle cross-section (Fig. 2) which is substantially at a right angle to blood flow direction of the blood vessel to which the column-shaped insertion part 22 is to be inserted with respect to the insertion stop part 26; wherein the elastic deformation at the elastic joint parts 32 allows the column-shaped insertion part 22 to have flexibility in puncturing angle to the blood vessel with respect to the wings 28, 30 (Figs. 1-2) the column-shaped insertion part 22 is to be inserted through the blood vessel; wherein the elastic deformation at the elastic joint parts 32 allows the column-shaped insertion part 22 of the insertion stop part 26 to have angular flexibility substantially in the rotating direction about the axis of the column-shaped part of the column-shaped insertion part 22 (Fig. 2) with respect to the wings 28, 30 (Figs. 1-2); wherein the elastic deformation at the elastic join parts 32 is set based on the material and the shape of the elastic joint parts 32 so that the balance with the elastic deformation for allowing the column-shaped

insertion part 22 to have flexibility in the puncturing angle to the blood vessel with respect to the wings 28, 30 and the elastic deformation for allowing the column-shaped insertion part 22 at the insertion stop part 26 to have angular flexibility substantially in the rotating direction about the axis of the column shaped insertion part 22 with respect to the wings 28, 30 are adjusted (Figs. 1-2); wherein the wings 28, 30 are connected to the insertion stop part 26 via flexible joint branches 32 (Figs. 1-2).

22. Regarding claim 9, Sasso discloses a jig for installing a pin 20 for forming a hole for inserting an indwelling needle comprising a main body 58 (Fig. 1) and a sliding body 22A (Fig. 1) that is built in the main body 58 for sliding in the longitudinal direction of the main body 58, a supporting means 26 (Fig. 1) for supporting the pin 20 for forming a hole for inserting an indwelling needle for holding the indwelling needle from the skin surface toward the blood vessel are provided at the distal end of the main body 58, the jig is for holding an indwelling needle 22 (Fig. 1) from a skin surface toward a blood vessel.

23. Regarding claims 10-11, Sasso further discloses wherein the main body 58 is integrally formed with two opposing side plates 28, 30 (Fig. 1) extending in parallel with each other, the sliding body 22A is fitted between the two side plates 28, 30 (via 26 - Fig. 1), a guide 26 engages the inner walls 32 of the two side plates 28, 30 which constitute the main body 58 and the outer wall which constitutes the sliding body 22A, and the sliding body 22A can slide forwardly of the main body 58 by forming the guide 26; wherein the sliding body 22A slidable inserted into a sliding shaft projecting from the distal end of the main body 58 (Fig. 1), two spring parts 28, 30 (Fig. 1) bending in the

outward direction of the main body 58 and the sliding body 22A, the two spring parts 28, 30 are fixed at the ends (via 32) thereof to the left and right side walls of the main body 58 (at '26' – Fig. 1) and the left and right side walls of the sliding body 22A respectively.

***Claim Rejections - 35 USC § 103***

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**25. Claims 2, 8, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasso (US Pat. No. 6,500,155 B2).**

26. Regarding claims 2 and 17, Sasso discloses all claimed elements including wherein elastic deformation at the elastic joint parts 32 (Fig. 1) is such that the entire wings 28, 30 can be moved in the direction of right angle cross-section (Fig. 2) which is substantially at right angle to blood flow direction of the blood vessel to which the column-shaped insertion part 22 is to be inserted with respect to the insertion stop part 26 (Figs. 1-2) **except for** wherein the insertion part is from 0.5 to 3.0 mm in outer diameter and is from 3 to 20 mm in length. It would have been an obvious matter of design choice to make the insertion part outer diameter 0.5 to 3.0 mm and the length 3 to 20 mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

27. Regarding claim 8, Sasso discloses all claimed elements **except for** wherein the joint branches are from 0.1 to 2 mm in diameter of the lateral cross-section, and 0.5 to 10 mm in length. It would have been an obvious matter of design choice to make the diameter of the joint branches 0.1 to 2 mm and the length 0.5 to 10 mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

28. **Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sasso (US Pat. No. 6,500,155 B2) in view of Shaw (US Pat. No. 5,779,679).**

29. Regarding claims 12-16, Sasso discloses all claimed elements **except for** wherein the sliding body is provided with driving means that allows the sliding body to slide along the main body; wherein the driving means used for the sliding body is using a finger stop part formed on a part of the sliding body; wherein the driving means for the sliding body comprises the finger stop part and the spring; the driving means for the sliding body is built in the tubular main body formed of left and right side walls, a bottom plate, a top plate, and a rear end wall, a coil spring is fitted between the interior of the rear end wall of the main body and the rear end of the sliding body so that the sliding body is energized forward, an upper part of the sliding body is formed with inclined plane facing a forwardly; an inclined plane facing rearwardly corresponding to said inclined plane is formed on the lower part of the finger stop part, and the upper part of the finger hook part projects above the main body through a through-hole formed on the top plate of the main body; wherein at least one part of the supporting means for

supporting the indwelling needle insertion hole-forming pin is retracted relatively rearward of the distal end of the main body in association with the sliding movement and the indwelling needle insertion hole-forming pin is separated from the supporting means; comprising a wing holding means for holding the wings of the indwelling needle insertion hole-forming pin at the distal end of the main body and/pr the distal end of the sliding body.

However, Shaw teaches a jig 10 for installing a pin for forming a hole for inserting an indwelling needle (Fig. 1) wherein a sliding body 32 (Fig. 1) is provided with a driving means 15 (spring; Fig. 1) that allows the sliding body 32 to slide along a main body 27 (Figs. 1-2); wherein the driving means 15 used for the sliding body 32 is using a finger stop part 36 (Figs. 1-2) formed on a part of the sliding body 32; wherein the driving means 15 for the sliding body 32 comprises the finger stop part 36 and a spring 15; the driving means 15 for the sliding body 32 is built in the tubular main body 27 (Figs. 1-2) formed of left and right side walls, a bottom plate, a top plate, and a rear end wall (Figs. 1-2), a coil spring 15 is fitted between the interior of the rear end wall of the main body 27 and the rear end of the sliding body 32 so that the sliding body 32 is energized forward, an upper part of the sliding body 32 is formed with inclined plane facing a forwardly; an inclined plane 40 facing rearwardly corresponding to said inclined plane 40 is formed on the lower part of the finger stop part 50, and the upper part of the finger hook part projects above the main body 27 through a through-hole 44 formed on the top plate of the main body 27; wherein at least one part of the supporting means 32 for supporting the indwelling needle insertion hole-forming pin is retracted relatively

rearward of the distal end of the main body 27 in association with the sliding movement (Figs. 1-2); comprising a wing holding means 44, 50 (Fig. 5) for holding the wings 40 (Fig. 4) of the indwelling needle insertion hole-forming pin at the distal end of the main body 27 (Fig. 2), in order to insert and maintain in place an IV and to allow for retraction of the needle (column 1, lines 5-9).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Sasso's device such that wherein the sliding body is provided with driving means that allows the sliding body to slide along the main body; wherein the driving means used for the sliding body is using a finger stop part formed on a part of the sliding body; wherein the driving means for the sliding body comprises the finger stop part and the spring; the driving means for the sliding body is built in the tubular main body formed of left and right side walls, a bottom plate, a top plate, and a rear end wall, a coil spring is fitted between the interior of the rear end wall of the main body and the rear end of the sliding body so that the sliding body is energized forward, an upper part of the sliding body is formed with inclined plane facing a forwardly; an inclined plane facing rearwardly corresponding to said inclined plane is formed on the lower part of the finger stop part, and the upper part of the finger hook part projects above the main body through a through-hole formed on the top plate of the main body; wherein at least one part of the supporting means for supporting the indwelling needle insertion hole-forming pin is retracted relatively rearward of the distal end of the main body in association with the sliding movement and the indwelling needle insertion hole-forming pin is separated from the supporting means; comprising a

wing holding means for holding the wings of the indwelling needle insertion hole-forming pin at the distal end of the main body and/pr the distal end of the sliding body, as suggested and taught by Shaw, for the purpose of inserting and maintaining in place an IV and to allow for retraction of the needle.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ASHLEY CRONIN whose telephone number is (571)270-7899. The examiner can normally be reached on monday-friday, 8am-5pm est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. C./  
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
9/30/2009